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Two-part bicarbonate containing solution and storage method useful as peritoneal dialysis solutions comprises e.g. sodium bicarbonate, sodium chloride, sodium lactate, glucose and calcium chloride

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Patent Family: 17 patents, 37 countries

Patent Number	Kind	Date	Application Number	Kind	Date	Update	Type
WO 2001017534	A1	20010315	WO 2000US20486	A	20000727	200119	B
AU 200063842	A	20010410	AU 200063842	A	20000727	200137	E
EP 1131077	A1	20010912	EP 2000950792	A	20000727	200155	E
			WO 2000US20486	A	20000727		
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			US 2001918328	A	20010730		
CN 1336825	**A**	**20020220**	**CN 2000802654**	**A**	**20000727**	**200235**	**E**
US 6475529	B2	20021105	US 1999393743	A	19990910	200276	E
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JP 2002370988	A	20021224	JP 2001167510	A	20010601	200315	NCE
BR 200102326	A	20030401	BR 20012326	A	20010608	200332	NCE
AU 779950	B2	20050224	AU 200063842	A	20000727	200520	E
CN 1147304	C	20040428	CN 2000802654	A	20000727	200610	E
TW 230068	B1	20050401	TW 2000117049	A	20000824	200634	E
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			WO 2000US20486	A	20000727		
DE 60030682	E	20061026	DE 60030682	A	20000727	200672	E
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Patent Details

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WO 2001017534	A1	EN	31	4		
National Designated States,Original	AT AU BR CA CH CN DE DK ES GB ID IN JP KR MX PT SE SG					
Regional Designated States,Original	AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE					
AU 200063842	A	EN			Based on OPI patent	WO 2001017534
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					Based on OPI patent	WO 2001017534
Regional Designated States,Original	AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI					
US 20020012707	A1	EN			Division of application	US 1999393743
					Division of patent	US 6309673
US 6475529	B2	EN			Division of application	US 1999393743
					Division of patent	US 6309673
JP 2002370988	A	JA	16			
BR 200102326	A	PT				
AU 779950	B2	EN			Previously issued patent	AU 200063842
					Based on OPI patent	WO 2001017534
TW 230068	B1	ZH				
EP 1131077	B1	EN			PCT Application	WO 2000US20486
					Based on OPI patent	WO 2001017534
Regional Designated States,Original	AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE					
DE 60030682	E	DE			Application	EP 2000950792
					PCT Application	WO 2000US20486
					Based on OPI patent	EP 1131077
					Based on OPI patent	WO 2001017534
ES 2272304	T3	ES			Application	EP 2000950792
					Based on OPI patent	EP 1131077
IN 200504509	P1	EN			PCT Application	WO 2000US20486
					Division of application	IN 2001DN428
DE 60030682	T2	DE			Application	EP 2000950792
					PCT Application	WO 2000US20486
					Based on OPI patent	EP 1131077
					Based on OPI patent	WO 2001017534

Alerting Abstract WO A1

NOVELTY - Two-part bicarbonate containing solution comprises a first part housed in a first container including an alkaline bicarbonate concentrate of pH 8.6-10.0 and a second part housed in a second container including an acidic concentrate of pH 1.0-3.0. The pH is selected so that when the two parts are mixed, the combined solution has a pH of 6.5-7.6.
DESCRIPTION - INDEPENDENT CLAIMS are included for a multi-chamber container for storing the two parts and stabilizing bicarbonate solutions by storing them in the multi-chamber container.
ACTIVITY - Nephrotropic.
No biological data given.
MECHANISM OF ACTION - None given.
USE - The solution is used in peritoneal dialysis using the patient's own peritoneum as a semipermeable membrane or hemofiltration, fluid is removed using a suitable osmotic gradient from the blood to the dialysate to permit water outflow from the blood. The balanced electrolyte solution is necessary to balance the water as an excessive amount of plasma water is eliminated by filtration. The present invention offers a method for storing and stabilizing bicarbonate-based peritoneal dialysis solutions.
ADVANTAGE - The solution does not require addition of carbon dioxide or the use of an expensive gas barrier material, nor is an organic acid needed. The invention allows for the production of sterile bicarbonate-based peritoneal solutions in a manufacturing plant at very low cost and to ship a chemically stable product to the hospital or patient's home. The two-part solution is stable for more than six months and is ready-to-use.
DESCRIPTION OF DRAWINGS - The figure illustrates a multi-chamber bag for storing a two-part bicarbonate solution. To mix the solution within the chambers the frangible connector must be broken.
10 Multi-chamber container
12 First chamber
14 Second chamber
16 Heat seal dividing the interior of the container
18 A frangible connector between the first and second chambers

Technology Focus
ORGANIC CHEMISTRY - Preferred Composition: The solution comprises an osmotic agent selected from glucose, glucose polymers, modified starch, amino acids, peptides and glycerol. The alkaline bicarbonate solution comprises sodium chloride, sodium lactate and sodium bicarbonate. The acidic concentrate comprises glucose, calcium chloride, magnesium chloride and an acid.

INORGANIC CHEMISTRY - Preferred Composition: The mixed solution comprises (mM): bicarbonate (5-45), calcium (0.2-2.0), sodium (100-150), magnesium (0-1.5), potassium (0-4.5), chloride (70-120), lactate (0-60) and acetate (0-60). The pH of the bicarbonate concentrate is adjusted with a base from pH 8.0-8.4 to 8.6-10 and the acid concentrate is adjusted with an acid to decrease the pH from 4.0-7.0 to 1.0-3.0. The container is constructed from a gas permeable material and is steam sterilized.

I. Original Publication Data by Authority

Original Abstracts:

The present invention provides devices and methods for stabilizing bicarbonate-based solutions for peritoneal dialysis or hemofiltration. The bicarbonate-based solutions of the present invention are formulated and stored in at least two parts - an alkaline bicarbonate concentrate and an acidic concentrate. The alkaline bicarbonate concentrate is adjusted to have a pH of about 8.6 to 10.0. The acidic concentrate is adjusted to have a stable, acidic pH ranging from about 1.0 to 3.0. Upon mixing, although some variation in the pH of the mixed bicarbonate solution exists, the inventors have discovered that with the appropriate selection of the parameters of the concentrates, the pH of the mixed solution is always within an acceptable physiological range.

The present invention provides devices and methods for stabilizing bicarbonate-based solutions for peritoneal dialysis or hemofiltration. The bicarbonate-based solutions of the present invention are formulated and stored in at least two parts--an alkaline bicarbonate concentrate and an acidic concentrate. The alkaline bicarbonate concentrate is adjusted to have a pH of about 8.6 to 10.0. The acidic concentrate is adjusted to have a stable, acidic pH ranging from about 1.0 to 3.0. Upon mixing, although some variation in the pH of the mixed bicarbonate solution exists, the inventors have discovered that with the appropriate selection of the parameters of the concentrates, the pH of the mixed solution is always within an acceptable physiological range.

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L'invention concerne des dispositifs et des procedes permettant de stabiliser les solutions bicarbonatees destinees a la dialyse peritoneale ou a l'hemofiltration. Ces solutions bicarbonatees sont formulees et conservees en au moins deux parties, soit un concentre de bicarbonate alcalin et un concentre acide. Dans le concentre de bicarbonate alcalin, le pH est regle entre 8,6 et 10,0 environ. Le concentre acide est regle de maniere a presenter un pH stable acide compris entre 1,0 et 3,0. Les inventeurs ont decouvert que grace a une selection appropriee des parametres des concentres, le pH

apres melange de cette solution bicarbonatee, en depit de quelques variations, se situe toujours dans une plage physiologiquement acceptable,.

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